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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/019,588 | 12/20/2001 | Frederic Andre | SANSYL002 | 1696 |

7590

03/26/2003

Patent Department
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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,588

Applicant(s)

ANDRE ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-9 and 11-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-4, 6-9 and 11-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

DETAILED ACTION

Election Requirement

1. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A matrix that is free of active substance and a matrix that contains active substance; and regarding the surfactants, cationic and zwitterionic surfactants are claimed; the delayed release coated core has alfuzosin active substance or hypnotic active substance.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

2. The claims are deemed to correspond to the species listed above in the following manner:

I. Claims 1-4, 7-9, 11-22 and 24-33 are directed to delayed release coated core where the surfactant is cationic, where the delayed release coated core is embedded in a rapidly

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disintegrating matrix that has an active substance and where the active substance in the delayed release coated core is alfuzosin.

II. Claims 1-4, 7-9, 11-22, 24-32 and 34 are directed to delayed release coated core where the surfactant is cationic, where the delayed release coated core is embedded in a rapidly disintegrating matrix that has an active substance and where the active substance in the delayed release coated core is a hypnotic.

III. Claims 1-4, 6-9, 11-22 and 24-33 are directed to delayed release coated core where the surfactant is zwitterionic, where the delayed release coated core is embedded in a rapidly disintegrating matrix that has an active substance and where the active substance in the delayed release coated core is alfuzosin.

IV. Claims 1-4, 6-9, 11-22, 24-32 and 34 are directed to delayed release coated core where the surfactant is zwitterionic, where the delayed release coated core is embedded in a rapidly disintegrating matrix that has an active substance and where the active substance in the delayed release coated core is a hypnotic.

V. Claims 1-4, 7-9, 11-23 and 25-33 are directed to delayed release coated core where the surfactant is cationic, where the delayed release coated core is embedded in a rapidly disintegrating matrix that is free of active substance and where the active substance in the delayed release coated core is alfuzosin.

VI. Claims 1-4, 7-9, 11-23, 25-32 and 34 are directed to delayed release coated core where the surfactant is cationic, where the delayed release coated core is embedded in a rapidly disintegrating matrix that is free of active substance and where the active substance in the delayed release coated core is a hypnotic.

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VII. Claims 1-4, 6-9, 11-23 and 25-33 are directed to delayed release coated core where the surfactant is zwitterionic, where the delayed release coated core is embedded in a rapidly disintegrating matrix that is free of an active substance and where the active substance in the delayed release coated core is alfuzosin.

VIII. Claims 1-4, 6-9, 11-23, 25-32 and 34 are directed to delayed release coated core where the surfactant is zwitterionic, where the delayed release coated core is embedded in a rapidly disintegrating matrix that is free of an active substance and where the active substance in the delayed release coated core is a hypnotic.

The following claim is generic: Claim 1 is generic.

3. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The special technical feature of an active substance is lacking in the rapidly disintegrating matrix in Groups IV-VIII. Groups I, II, V and VI lack zwitterionic technical feature and Groups II, IV, VI and VIII lack the active substance alfuzosin.

4. A telephone call was made to Paul Dupont on 3/13/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600
March 24, 2003

A handwritten signature in black ink, appearing to read "B. Fubara", is written over the printed name "Blessing Fubara".